IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

JANE RENE' SILVER, Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS, INC., Defendant.	)	No. 2:19-cv-3495-DCN-MHC **ORDER**

This matter is before the court on Magistrate Judge Molly H. Cherry's report and recommendation ("R&R"), ECF No. 125, that the court grant in part and deny in part defendant Bayer Healthcare Pharmaceuticals, Inc.'s ("Bayer") motion to dismiss, ECF No. 98. For the reasons set forth below, the court adopts in part and rejects in part the R&R and grants in part and denies in part Bayer's motion to dismiss.

I. BACKGROUND

The R&R ably sets forth the facts and procedural history of this case, and the parties do not object to the R&R's rendition of those facts. Therefore, the court dispenses with a lengthy recitation thereof and instead briefly recounts those facts material to its review. This case is about Eovist, a gadolinium-based contrast agent ("GBCA") approved by the Food and Drug Administration ("FDA") and administered intravenously by medical professionals for diagnostic purposes. Eovist is intended to enhance the quality of magnetic resonance imaging ("MRI") of the liver to diagnose serious conditions such as cancer. The FDA approved Eovist for use in 2008. It is manufactured, sold, and marketed by Bayer.

In 2016, doctors referred plaintiff Jane Rene' Silver ("Silver") to a local hospital for an MRI to further examine lesions that had been discovered on her liver by an ultrasound. Silver's radiologist was concerned that the lesions were cancerous but expressed that the "only way" to know "is by using the GBCA Eovist." ECF No. 75, Amend Compl. ¶ 1. Despite her concern that Eovist would be retained in her system, Silver contracted with Bayer to provide Eovist for a basic MRI at her local hospital, Tidelands Waccamaw Hospital in Murrells Inlet, South Carolina. She was injected with Eovist on December 30, 2016. Silver alleges that within a week, she began experiencing "unexplained symptoms," including "[e]xplosive flatulence, random sour spittle, random knuckle bleeding, random red eyes, groin pain, rib pain, brain fog, edema in the right arm . . . fibrosis covering a finger and part of a hand, very stiff muscles[,] and skin tightening." Amend. Compl. ¶ 2. Silver alleges that in June 2017, she lost her job because she was unable to complete tasks that she had previously been able to do before the injection.

Six months after she received the Eovist injection, Silver claims to have discovered that she had retained gadolinium—a metal element found in Eovist and other similar GBCAs—in her system. Silver alleges that this retention caused her to develop "Gadolinium Deposition Disease" ("GDD"). Even before she was injected with Eovist, Silver had expressed concern about possible metal retention to her radiologist. Silver also alleges that two years after Silver received an injection, Bayer added a label to Eovist—effective April 26, 2018—warning about the long-term retention of gadolinium in people with healthy kidneys. The Eovist label that was in effect on December 30,

2016—the date Silver received the Eovist injection—had been approved by the FDA in March 2015.

On December 17, 2019, Silver, proceeding pro se, filed the instant action against Bayer, CVS Health One, and McKesson Specialty. ECF No. 1. CVS Health One and McKesson Specialty were ultimately dismissed from the case. ECF No. 129. On November 17, 2020, Silver filed her second amended complaint, now the operative complaint, alleging: (1a) design defect; (1b) manufacturing defect; (1c) warnings defect; (2) punitive damages; (3) breach of express warranty; (4) strict liability; (5) criminal and gross negligence; (6) tolling, fraudulent concealment, and omission; (7) mens rea; (8) nonfeasance and/or misfeasance; and (9) personal injury.[1] Amend. Compl. at 9. Pursuant to 28 U.S.C. §§ 636(b)(1)(A) and (B) and Local Civil Rule 73.02(B)(2)(g) (D.S.C), all pretrial proceedings in this case were referred to Magistrate Judge Cherry.

On January 15, 2021, Bayer filed a motion to dismiss on all of Silver's claims. ECF No. 98. Silver responded to the motion on March 16, 2021, ECF No. 115, and Bayer replied on April 30, 2021, ECF No. 121.[2] On June 10, 2021, Magistrate Judge Cherry issued the R&R, recommending that the court grant in part and deny in part the motion to dismiss. ECF No. 125. On July 27, 2021, Bayer filed objections to the R&R. ECF No. 140. Silver responded to the objections on August 27, 2021, ECF No. 143, and Bayer replied on August 31, 2021, ECF No. 144. Silver did not object to the R&R, and

[1] Silver renumbered her claims between the second amended complaint and the response to Bayer's objections to the R&R. Compare Amend. Compl. at 9 with ECF No. 143 at 3–13. The court uses the numbers as they appear in the amended complaint.

[2] Silver filed a sur-reply without seeking leave of the court. ECF No. 122. As the R&R correctly noted, the court need not consider the sur-reply as it is not properly before the court. ECF No. 125 at 1 n.1 (citing Stanfield v. Charleston Cnty. Ct., 2015 WL 4929186, at *4 n.2 (D.S.C. Aug. 18, 2015)).

the time to do so has now expired.[3] As such, the matter is now ripe for the court's review.

II. STANDARD

A magistrate judge makes only a recommendation to the court. Mathews v. Weber, 423 U.S. 261, 270 (1976). The recommendation carries no presumptive weight, and the responsibility to make a final determination remains with the court. Id. at 270-71. The court may "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge . . . or recommit the matter to the magistrate judge with instructions." 28 U.S.C. § 636(b)(1). The court is charged with making a de novo determination of any portion of the R&R to which a specific objection is made. Id. However, in the absence of a timely filed, specific objection, the court reviews the R&R only for clear error. Diamond v. Colonial Life & Accident Ins. Co., 416 F.3d 310, 315 (4th Cir. 2005) (citation omitted). Furthermore, "[a] party's general objections are not sufficient to challenge a magistrate judge's findings." Greene v. Quest Diagnostics Clinical Labs., Inc., 455 F. Supp. 2d 483, 488 (D.S.C. 2006) (citation omitted). When a party's objections are directed to strictly legal issues "and no factual issues are challenged, de novo review of the record may be dispensed with." Orpiano v. Johnson, 687 F.2d 44, 47 (4th Cir. 1982) (citation omitted). Analogously, de novo review is unnecessary when a party makes general and conclusory objections without

[3] Silver previously filed objections, ECF No. 131, to the R&R on McKesson Corporation and South Carolina CVS Pharmacy's motion to dismiss, ECF No. 123. The court has thoroughly reviewed those objections and determined that they do not raise any specific objections to the R&R on Bayer's motion to dismiss, ECF No. 125.

directing a court's attention to a specific error in a magistrate judge's proposed findings. Id.

A Rule 12(b)(6) motion for failure to state a claim upon which relief can be granted "challenges the legal sufficiency of a complaint." Francis v. Giacomelli, 588 F.3d 186, 192 (4th Cir. 2009) (citations omitted); see also Republican Party of N.C. v. Martin, 980 F.2d 943, 952 (4th Cir. 1992) ("A motion to dismiss under Rule 12(b)(6) . . . does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses."). To be legally sufficient, a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A Rule 12(b)(6) motion should not be granted unless it appears certain that the plaintiff can prove no set of facts that would support his claim and would entitle him to relief. Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993). When considering a Rule 12(b)(6) motion, the court should accept all well-pleaded allegations as true and should view the complaint in a light most favorable to the plaintiff. Ostrzenski v. Seigel, 177 F.3d 245, 251 (4th Cir.1999); Mylan Labs., Inc., 7 F.3d at 1134. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

Petitioner is proceeding pro se in this case. Pro se complaints and petitions should be construed liberally by this court and are held to a less stringent standard than

those drafted by attorneys. See Gordon v. Leeke, 574 F.2d 1147, 1151 (4th Cir. 1978), cert. denied, 439 U.S. 970, 99 (1978). A federal district court is charged with liberally construing a complaint or petition filed by a pro se litigant to allow the development of a potentially meritorious case. See Hughes v. Rowe, 449 U.S. 5, 9 (1980). Liberal construction, however, does not mean that the court can ignore a clear failure in the pleading to allege facts that set forth a cognizable claim. See Weller v. Dep't of Soc. Servs., 901 F.2d 387, 390–91 (4th Cir. 1990).

III. DISCUSSION

The Magistrate Judge recommended that the court grant the motion to dismiss in Bayer's favor on the following claims: manufacturing defect (Count 1b); punitive damages (Count 2); breach of express warranty (Count 3); tolling, fraudulent concealment, and omission (Count 6); mens rea (Count 7); nonfeasance and malfeasance (Count 8); and personal injury (Count 9). No party filed objections to the R&R with respect to these counts. Therefore, the court "must only satisfy itself that there is no clear error on the face of the record in order to accept the recommendation." Diamond, 416 F.3d at 315 (internal quotations and citation omitted). After reviewing the record in this case, the applicable law, and the R&R, the court finds no clear error in the R&R's finding that Silver failed to state a claim as to these counts. The court therefore adopts the R&R and dismisses Counts 1b, 2, 3, 6, 7, 8, and 9.

The Magistrate Judge further recommended that the court deny the motion to dismiss on the following claims: pre-FDA-approval design defect (Count 1a); warning defect (Count 1c); strict liability (Count 4); and gross negligence (Count 5). Bayer only objects to the R&R as to these counts. The court addresses each of Bayer's objections in

turn, and then addresses Bayer's motion to dismiss due to an alleged violation of Federal Rule of Civil Procedure 8(a).[4]

A. Design Defect Claim (Count 1a)

Under Count 1a, design defect, Silver alleges that the design and creation of Eovist was defective in three different ways: (1) "it is a linear design, which many studies and scientific papers have proven to be less safe and less stable" and leads to retention "more often than Macrocyclic design"; (2) "it is designed to clear half from the Liver and half from the Kidneys," even though "it is recommended for Liver Scans, in which people with compromised Livers are being scanned"; and (3) "there was no warning of its insufficiency, . . . its history of being retained in those with healthy kidneys was not disclosed," and the warning "did not state that the Linear products were not as stable or safe as Macrocyclic products." Amend. Compl. at 9–10. In its objections, Bayer argues that the R&R incorrectly declined to dismiss Silver's claim after Bayer had shown that Silver's design defect claim is preempted by federal law, ECF No. 98 at 18, and in any case, the claim independently fails under state law because Silver failed to plead an injury and because Silver failed to show a reasonable alternative design for Eovist. The court addresses each of Bayer's arguments in turn.

[4] Silver's second amended complaint totals over 1,200 pages. The court also notes, as the R&R did, that the attached exhibits were not part of Silver's initial complaint, and she did not obtain approval to include them in her amended complaint. ECF No. 125 at 2–3. In any case, the court only draws its attention to those documents and excerpts that Silver references in her second amended complaint. Judges are not like pigs, hunting for truffles buried in briefs. United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991).

1. Preemption

State law may be preempted under the Supremacy Clause of the United States Constitution through express preemption, field preemption, and conflict "implied" preemption. See English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990). Implied preemption arises when a state law conflicts with a federal law. See Maryland v. Louisiana, 451 U.S. 725, 746 (1981). For example, the Supreme Court has found preemption "where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id. Accordingly, the Fourth Circuit has stated that "[p]reemption is fundamentally a question of congressional intent." Wilmington Shipping Co. v. New England Life Ins. Co., 496 F.3d 326, 341 (4th Cir. 2007).

Congress did not authorize the FDA to directly preempt state lawsuits. Wyeth v. Levine, 555 U.S. 555, 581 (2009). Instead, the Supreme Court has recognized that in general, state tort suits complement FDA regulation and better advance public health. Id. at 578–79. As a result, FDA regulations are generally seen as a floor, rather than a floor and a ceiling. Id. at 577–78.

The R&R determined that it could proceed to analyze Silver's design defect claim under South Carolina law because it was not preempted by FDA regulations. Preemption analysis requires a comparison of federal and state law to determine if they are in conflict. PLIVA, Inc. v. Mensing, 564 U.S. 604, 611 (2011). Under South Carolina law, "[a] plaintiff proceeding under a design defect claim . . . must 'point to a design flaw in the product and show how h[er] alternative design would have prevented the product from being unreasonably dangerous.'" Priester v. Futuramic Tool & Eng'g Co., 2017

WL 1135134, at *4 (D.S.C. Mar. 27, 2017) (quoting Graves v. CAS Med. Sys., Inc., 735 S.E.2d 650, 658 (S.C. 2012)). The allegedly conflicting FDA regulation is 21 C.F.R. § 314.70(b)(2)(i). See ECF No. 98 at 8 (citing statute). This provision provides that once a drug is approved, "the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product'" without FDA approval. Mut. Pharm. Co., Inc. v. Barlett, 570 U.S. 472, 477 (2013) (quoting statute). The R&R found it useful to consider Silver's claim under three periods in which Bayer may have allegedly violated this rule. The court will do the same for purposes of addressing Bayer's objections.

a. Stop-Selling Theory

Silver claims that due to the design defect of Eovist, it "should have been banned" by Bayer. Amend. Compl. at 13. Bayer argues that this constitutes a "stop-selling" theory, which courts have consistently found to be preempted by federal law. ECF No. 98 at 19. The R&R agreed "that any claim that Bayer should have simply stopped selling Eovist is preempted" and dismissed the claim on this ground. ECF No. 125 at 20 (citing In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig., 185 F. Supp. 3d 761, 771 (D.S.C. 2016)).

The Supreme Court has rejected the "stop-selling" theory as incompatible with preemption jurisprudence because "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" Mut. Pharm. Co., Inc. v. Bartlett, 570 U.S. 472, 488 (2013) (quoting Mensing, 564 U.S. at 621). In other words, there would never be any direct conflict between federal and state laws if a plaintiff could simply demand the regulated actor cease acting. Id. Neither party raises

an objection to the R&R's finding that Silver's design defect claims ought to be preempted to the extent they request that Bayer stop selling Eovist altogether. ECF No. 140 at 23. The court finds no clear error with the R&R's recommendation to reject Silver's stop-selling theory of alternative design.

b. Claim that Bayer should have changed the design after FDA approval

The R&R found that pursuant to South Carolina law, Silver proposed an alternative design which involved switching from a linear design to a macrocyclic design, and such a major change in design would have necessitated FDA approval under 21 C.F.R. § 314.70(b)(2)(i). ECF No. 125 at 20–21. Bayer has no objection to the R&R's finding. ECF No. 140 at 23. Applying a clear error lens, the court again agrees that to the extent Silver alleges that state law required Bayer to change to an alternative design after Eovist was approved by the FDA in 2008, such a claim is preempted.

c. Claim that Bayer should have changed the design pre-approval

Finally, the R&R found that Silver is permitted to bring a design defect claim to the extent she argues that Bayer should have designed Eovist in an alternate way before it was even approved by the FDA. ECF No. 125 at 21. "[V]iewing the Amended Complaint liberally," the Magistrate Judge found that Silver had advanced this argument when she stated that "[t]he design defect had three parts that were defective in the creation of . . . Eovist." Id. (quoting Amend. Compl. at 10). The R&R went on to find that the Supreme Court has not addressed whether federal law preempts design defect claims on the grounds that, prior to initial FDA approval, the drug should have had a different composition, and courts are split on the issue. Id. (citing Holley v. Gilead Scis.,

Inc., 379 F. Supp. 3d 809, 822 (N.D. Cal. 2019)). Therefore, the R&R determined that ruling on the issue of whether Bayer should have used a different design for Eovist before it gained FDA approval was not appropriate at the motion to dismiss stage.

Bayer objects to this conclusion, arguing that as a preliminary matter, Silver did not actually plead a design-defect claim based on pre-FDA approval design. ECF No. 140 at 23 n.19. Although the court agrees it is possible that Silver did not fully intend to plead a pre-FDA approval design defect, that is not the standard by which the court must review the pleading. Silver alleges that "[t]he design defect had three parts that were defective in the creation of . . . Eovist." Amend. Compl. at 10 (emphasis added). By stating that the drug was defective at creation, Silver plausibly makes a claim that the drug was defective at that time—and needed to have been different prior to FDA approval or risk being unreasonably dangerous. Bayer states that the phrase "the creation of" in Silver's complaint clearly refers to the general "making" of the product and not necessarily the first design, evidenced by the fact that the rest of Silver's complaint did not refer to a theory that Bayer should have submitted a different design of Eovist to the FDA. ECF No. 140 at 23 n.19. But district courts that have recognized claims for pre-approval design defects have analyzed it as an issue of whether the "manufacturer was required to use the allegedly defective design in the first place." Trahan v. Sandoz, Inc., 2015 WL 2365502, at *6 n.5 (M.D. Fla. Mar. 26, 2015). If the court were to adopt the same view then, Silver has pled some facts to support the claim.

Second, and more prominently, Bayer argues that the court erred because even the approval of an initial design would require the FDA's special permission and assistance, thus preempting state law. ECF No. 140 at 23. To support this proposition, Bayer cites

cases from outside the Fourth Circuit where courts dismissed pre-approval design-defect claims. Id. at 23–24 (citing Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.3d 281, 300 (6th Cir. 2015)). While Yates stands for such a proposition, it is directly contravened by other courts, meaning there is a split in authority on the issue. On one side, some courts have shared the Yates view and found that a company cannot be considered to have altered the composition of a drug without prior approval of the FDA in the first place. See also Utts v. Bristol-Myers Squibb Co., 226 F. Supp. 3d 166, 186 (S.D.N.Y. 2016). On the other side, courts have allowed such claims to proceed because they determined that the question turns on whether a drug manufacturer could "independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval." Guidry v. Janssen Pharms., Inc., 206 F. Supp. 3d 1187, 1208 (E.D. La. Aug. 29, 2016). No court within the Fourth Circuit has weighed in.

In response to the split in authority, Bayer argues that the opinions that the R&R relied upon "fail to explain how a pre-approval design-defect claim can overcome the preemption hurdles in Mensing and Yates." ECF No. 140 at 26. Bayer ignores the cases that do just that. See Guidry, 206 F. Supp. 3d at 1208 (rejecting defendants' reliance on Mensing in arguing that pre-approval design-defect claim was preempted); Holley, 379 F. Supp. 3d at 824 ("The Court rejects the Yates court's 'too attenuated' theory . . ."); Young v. Bristol-Myers Squibb Co., 2017 WL 706320, at *8 (N.D. Miss. Feb. 22, 2017) (stating that Yates misapplied the stop selling rationale to pre-approval design-defect claims). Bayer circularly reasons that the Holley court—which surveyed all of the cases addressing the issue—incorrectly analyzed the question of whether the claims are preempted because it failed to recognize that drug manufacturers must seek FDA

approval to comply with its state-law duties. However, the Holley court specifically addressed why it did not need to limit itself to that interpretation. See Holley, 379 F. Supp. 3d at 824.

Nevertheless, the court agrees with the Magistrate Judge that the court need not determine which side of the split this court comes out on. Several tools suggest this is the proper finding. First, while the Sixth Circuit in Yates is the only Court of Appeals to have ruled on the issue, the majority of courts have found no preemption in this context. Holley, 379 F. Supp. 3d at 822–823. Since no Fourth Circuit court has weighed in, neither result is more persuasive. Second, the Supreme Court has counseled that in considering whether a manufacturer can comply with both state and federal law, courts must determine a manufacturer's duties under the state law for comparison. Bartlett, 570 U.S. at 480 ("We begin by identifying a petitioner's duties under state law."). Here, South Carolina's law requires that a plaintiff "point to a design flaw in the product" and show how an alternative design would have prevented it from being unreasonably dangerous. Thus, unlike other jurisdictions, there is no knowledge-based element and there is nothing that suggests courts must analyze whether the manufacturer should "alter" the composition. See Gremo v. Bayer Corp., 469 F. Supp. 3d 240, 256–57 (D.N.J. June 29, 2020) (distinguishing "state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by . . . altering its composition"). As such, the rule is not inconsistent with the reading that the initial design must have been reasonably safe. Third, even courts which have recognized pre-approval design-defect claims have determined that the question is more of a "matter[] for post-discovery dispositive-motion practice, not a motion for judgment on the pleadings." Small v.

Amgen, Inc., 2016 WL 4942078, at *2 (M.D. Fla. Jan. 25, 2016). Bayer fails to respond to this finding in the R&R in its objections and instead, argues that the R&R ignored "numerous opinions" which have dismissed GBCA design-defect claims at the pleading stage. ECF No. 140 at 25. None of the cases Bayer cites addressed the question of whether the plaintiff could have proceeded with a state law claim on the grounds that the drug in question should have been designed differently before it received FDA approval; instead, they discussed how post-approval design defect claims and stop-selling rationales are either preempted or incompatible, which the court has already stated is correct. See Javens v. GE Healthcare Inc., 2020 WL 2783581, at *6 (D. Del. May 29, 2020); Drescher v. Bracco Diagnostics Inc., 2020 WL 699878, at *7 (D. Ariz. Jan. 31, 2020) ("The Amended Complaint does not allege that Defendants should have designed their drugs differently prior to seeking FDA approval . . . ."); Thomas v. Bracco Diagnostics Inc., 2020 WL 1016273, at *8 (W.D. La. Feb. 27, 2020) ("Thomas's complaint does not implicate the pre-FDA approval stage."). Ultimately, the court agrees that whether Silver's claim should be preempted is a matter for post-discovery dispositive motion practice and not a motion to dismiss. The court therefore adopts the R&R's recommendation and denies Bayer's motion to dismiss on preemption grounds.

2. State Law Claim

Since the court does not find that Silver's state law claims are preempted at this stage of litigation, the court turns to the substantive elements of Silver's claims. Before turning to the merits of Silver's design defect claim, the court first addresses the law on product products liability in general, which is applicable to each of Silver's products liability claims. Under any products liability theory, a plaintiff must establish:

> (1) [s]he was injured by the product; (2) the product was in essentially the same condition at the time of the accident as it was when it left the hands of the defendant, and (3) the injury occurred because the product "was in a defective condition unreasonably dangerous to the user."

Graves, 735 S.E.2d at 658 (quoting Madden v. Cox, 328 S.E.2d 108, 112 (S.C. Ct. App. 1985)). The R&R determined that Silver had established each element under the minimum pleading standards. In response, Bayer contends that Silver failed to plead an injury because the mere retention of gadolinium is not a legally cognizable injury. Bayer cites South Carolina cases that explain that mere "medical monitoring," where plaintiffs sue based on speculative future harm, is insufficient. ECF No. 140 at 27–28. As the R&R noted, however, Silver alleges that the retention of gadolinium has resulted in fibrosis, brain fog, edema, neuropathy, and bone pain. Amend. Compl. ¶ 2; see ECF No. 75-4 at 2–3. In its objections, Bayer claims these are "alleged symptoms" of gadolinium retention, which cannot be separated from the concept that retention alone cannot constitute a freestanding, legally cognizable injury. ECF No. 140 at 28. In essence, Bayer attempts to argue that since GDD is a fictional disease, ECF No. 140 at 4, all the symptoms alleged by Silver must be so as well. Courts have rejected this view outright. See, e.g., Pierik v. GE Healthcare Inc., 2019 WL 4686551, at *2 (N.D. Ill. June 18, 2019) ("[P]laintiffs have alleged plausible injuries in the form of [plaintiff]'s fibrosis resulting from gadolinium retention . . . ."). Even if gadolinium retention was the only injury that Silver pled, courts have found that it is inappropriate to determine whether it is, in fact, an injury at the motion to dismiss stage. E.g., Dennis v. Bayer Healthcare Pharms. Inc., 2020 WL 534307, at *6 (W.D.N.C. Feb. 3, 2020) ("[Defendant]'s argument that gadolinium retention is not an injury prematurely challenges the merits of Plaintiff's claims. Whether gadolinium retention is an injury or whether there is any causal link

between gadolinium deposition and any disease cannot be resolved on the pleadings."). Without citing any additional authority, Bayer claims that this view is part of the "small minority of opinions ruling that this issue cannot be decided at the motion-to-dismiss stage." ECF No. 140 at 28 n.22. The court finds Bayer's contention unsupported and that Silver has sufficiently pled injury.

Bayer also argues that the R&R incorrectly concluded that the alleged injuries were reasonably foreseeable. The court disagrees with Bayer's statements for the same reasons as stated above. "Whether the gadolinium retention creates a 'reasonable probability' of future injury is a fact-intensive inquiry not appropriate for resolution on the pleadings." Goodell v. Bayer Healthcare Pharm. Inc., 2019 WL 4771136, at *5 (D. Mass. Sept. 30, 2019). Therefore, the court finds that Silver has sufficiently pled a general products liability action.

Regarding Silver's manufacturing defect claim specifically, the R&R found that Silver has sufficiently pled a manufacturing defect and permitted the claim to proceed. As discussed supra, under South Carolina law, "[a] plaintiff proceeding under a design defect claim in South Carolina must 'point to a design flaw in the product and show how h[er] alternative design would have prevented the product from being unreasonably dangerous.'" Priester, 2017 WL 1135134, at *4. Bayer objects to the R&R's finding, arguing that Silver failed to plead a reasonable alternative design.

As discussed earlier, Silver alleges in her amended complaint that Eovist should have been designed as a macrocyclic GBCA rather than as a linear GBCA. Amend. Compl. at 10. In response, Bayer contends that this is a "threadbare allegation[]" which "offers no details of how such a design is even possible" or "any consideration of the

costs, safety and functionality." ECF No. 140 at 31 (quoting Branham v. Ford Motor Co., 701 S.E.2d 5, 16 (S.C. 2010)). But Bayer ignores that its own cited authority states these are considerations for trial. See Branham, 701 S.E.2d at 16 n.16 (noting the analysis asks the trier of fact to balance the price, utility, and safety concerns with the benefits of the alternative design); id. at 16–17 ("On retrial, Branham's design defect claim will proceed pursuant to the risk-utility test . . . ."). The court finds that such questions are better reserved for summary judgment proceedings after the parties have had the benefit of discovery. Finally, Bayer objects that Silver only provides "scattered remarks" about macrocyclic GBCAs instead of "facts showing how Eovist could have been designed differently while still serving its diagnostic purpose." ECF No. 140 at 32. However, Silver sufficiently alleges in her pleadings that the macrocyclic design is well-established; it is not one of Silver's own machinations. The court finds that Silver has "identif[ied] a specific design approach that has been implemented elsewhere in the industry" and provided some evidence that it can be implemented for Eovist. Wickersham v. Ford Motor Co., 194 F. Supp. 3d 434, 440 (D.S.C. 2016). For purposes of the motion to dismiss, the court finds that Silver has presented sufficient evidence of a feasible alternative design. The court permits Silver's design defect claim to proceed.

B. Warning Defect (Count 1c)

Silver alleges that she should have been provided with nine different warnings, and Bayer's failure to do so constituted warning defects. Amend. Compl. ¶ 1. The R&R recommended dismissing six of the warning defects claims at the outset because Silver's allegations in her amended complaint only went on to address three of them. ECF No. 125 at 14 n.11. Those three warnings actually pled by Silver are: (1) "Retention in

patients with healthy kidneys"; (2) "Linear Design shown to retain and promote Gadolinium caused diseases more often than Macrocyclic Design"; and (3) "Can Cause Gadolinium-induced diseases for which there are no known cures." Id. at 13; Amend. Compl. ¶ 1. Neither Bayer nor Silver object to the recommendation, and the court agrees that the other six alleged warning defects are not supported by any factual allegations. Therefore, the court adopts the R&R in this respect and dismisses these six warning defect claims. For Silver's remaining warning defect claims, Bayer challenges the R&R's findings that federal drug regulations governing the label content did not preempt Silver's state law claim and that Silver's claim could proceed under state law. ECF No. 140 at 2–4. The court addresses each in turn.

1. Preemption

As discussed earlier, implied preemption arises when a state law conflicts with a federal law, such as when it is impossible for a party to comply with both state and federal requirements. As it did before, the court begins by comparing the state and federal laws to determine if there is a conflict. Under South Carolina law, "[w]hen a warning defect claim is made, a plaintiff alleges that he was not adequately warned of dangers inherent to a product." Watson v. Ford Motor Co., 699 S.E.2d 169, 174 (S.C. 2010). On the federal side, "[w]hen Congress enacted the Federal Food, Drug, and Cosmetic Act ["FDCA"] . . . 21 U.S.C. § 301 et seq., it charged the [FDA] with ensuring that prescription drugs are 'safe for use . . . in the drug's labeling.'" Merck Sharp & Dohme Corp. v. Albrecht, 139 S.Ct. 1668, 1672 (2019) (citing 21 U.S.C. § 355(d)). Federal law requires FDA approval of a New Drug Application prior to marketing a new drug in the United States. Following approval of a prescription drug, a drug

manufacturer may only unilaterally alter a drug's label if it either (1) secures FDA approval or (2) makes a change under the Changes Being Effected ("CBE") regulation. In re Lipitor, 185 F. Supp. 3d at 768 (citing 21 C.F.R. §§ 314.70(b); 314.70(c)(6)(iii)). Even if a manufacture does change the label text unilaterally per CBE regulation, the FDA can still "reject CBE submissions and require manufacturers to revert to the prior version of the label." Dolin v. GlaxoSmithKline LLC, 901 F.3d 803, 812 (7th Cir. 2018). The burden is on the defendant to show it is impossible the comply with the federal regulatory scheme and state warning requirements. Sabol v. Bayer Healthcare Pharm., Inc., 439 F. Supp. 3d 131, 147 (S.D.N.Y. 2020) (citing Wyeth, 555 U.S. at 573). Therefore, Bayer must either (1) demonstrate that Silver fails to allege facts showing that Bayer could have unilaterally changed Eovist's label under CBE regulation, or (2) present clear evidence that the FDA would not have approved a change to the drug's label. See id. (citing Wyeth, 555 U.S. at 568–73)).

The R&R analyzed Silver's allegations under each independent method in which Bayer could have made changes to Eovist's label without implicating federal law—which would make Bayer subject to the state claim. Bayer asserts its objections in the same manner, so the court will proceed in the same manner.

a. The CBE Regulation

The R&R determined that Silver's claim may proceed because she has plausibly pled facts alleging that Bayer could have changed the label under CBE regulation.

Alterations to drug labels are permitted under CBE regulation "to reflect newly acquired information" if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the

standard for inclusion under § 201.57(c)." 21 C.F.R. § 314.70(c)(6)(iii)(A). The newly acquired information must provide "reasonable evidence of a causal connection" of a "clinically significant adverse reaction[]" to the drug. Id. at § 201.57(c)(6)(i). A clinically significant adverse reaction includes one that is "potentially fatal," "serious even if infrequent," or can "be prevented or mitigated through appropriate use of the drug." Id. The limitations are not meant to warrant the "inclusion of speculative or hypothetical risks that could discourage appropriate use of a beneficial drug." Albrecht, 139 S. Ct. at 1673 (internal quotations and citation omitted).

i. Objection a

Both the R&R and the objections first address whether there was any "newly acquired information." ECF No. 125 at 14; ECF No. 140 at 11. The R&R agreed with Bayer's assertion in its motion to dismiss that to satisfy the CBE regulation, Silver must allege that new information arose sometime after March 2015—when the FDA had last approved Eovist's label—and December 2016—when Silver was injected with Eovist. ECF No. 125 at 12–13 (citing ECF No. 98 at 11). The court agrees that only during this period could Bayer have been expected to correct its label in a way that would have affected Silver. Any information known before March 2015 would have been reflected in the label already and would not be "newly acquired." Any new information that came after December 2016 could not have been available at the time of Silver's procedure.

Many of Bayer's objections contend that certain other articles cited by Silver were published after Silver used Eovist on December 30, 2016. E.g., ECF No. 140 at 16. Based on the discussion above, the court agrees that those studies containing allegedly new information outside this time-period are not relevant. But the R&R also points to

multiple documents attached to Silver's amended complaint that, "in fact, allege newly acquired information . . . that arose between March 2015 and December 2016." ECF No. 125 at 14 (citing ECF No. 115 at 14). Specifically, the R&R references no less than five pieces of literature provided by Silver that fall within the proper timeframe. Id. at 14–15 (citing literature reviews and case studies from January 2016, March 2015, April 2016, October 2016, and August 2016). The court overrules Bayer's objections as to the allegations based on those five articles but agrees that Silver cannot argue that Bayer acquired any new information for which it was required to alter its drug label based on any other sources.

ii. Objection b

In response to the articles that were published within the appropriate time-period, Bayer asserts that even if these articles did constitute newly-acquired information, the R&R incorrectly determined that the articles satisfied the standard for proving that gadolinium retention "causes any 'clinically significant' 'hazard' or 'adverse reaction[]' for patients with normal kidney function" or causes the symptoms Silver allegedly experienced. ECF No. 140 at 13. Specifically, Bayer criticizes the studies because they only address "the retention of gadolinium" and "not any negative health consequences resulting from retention." Id. at 14.

Regarding the alleged warning defects for failure to disclose that a linear design causes disease more often than a macrocyclic design and that Eovist can cause gadolinium-induced diseases, Silver cited some literature that described or implied serious adverse effects which are enough to plausibly meet the standard set forth by the CBE regulations at this stage. For example, Silver cited an October 2016 study which

reported on "patients with normal renal function who developed clinical symptoms arriving shortly after receiving GBCA administration" and an August 2016 study proposing the term "gadolinium deposition disease" to describe "a new entity that represents symptomatic deposition of gadolinium in individuals with normal renal function." Amend. Compl. at 31. Bayer attacks the October 2016 and August 2016 sources, arguing that, for example, the October 2016 study only included four patients, and such a study is insufficient to satisfy the causal standard under CBE regulation. ECF No. 140 at 15. These forms of disputes are precisely the type that are better reserved for later proceedings, when the court can appropriately weigh the evidence. See Tobey v. Jones, 706 F.3d 379, 387 (4th Cir. 2013) (stating a motion to dismiss under Rule 12(b)(6) "does not resolve contests surrounding the facts, the merits of a claim or the applicability of defenses"). In any event, the case Bayer cites, Rayes v. Novartis Pharms. Corp., 2021 WL 2410677 (C.D. Cal. June 11, 2021), is distinguishable. There, the court stated that "three to ten individual reports" acquired by the defendant during the newly acquired information window would not have "reasonably enabled Defendant to unilaterally change its labeling." Id. at *6. Here, however, the study carried the significance and weight of a published clinical study. Such studies are more impactful to a company like Bayer than individual complaints, and Bayer could reasonably have expected that it would be able to unilaterally alter its Eovist label under CBE regulation. The court overrules Bayer's objection; viewing the facts in the light most favorable to Silver, Silver sufficiently alleges an "adverse reaction" and "evidence of a causal association."

iii. Objection c

Finally, Bayer states in its objections that the R&R failed to consider its argument that the FDA was already aware of all information pled by Silver, and thus, such information could not have been "newly acquired." ECF No. 140 at 17. "[N]ewly acquired information, as the term is defined in 21 C.F.R. § 314.3(b) . . . must have 'reveal[ed] risks of a different type or greater severity or frequency than previously included in submissions to the FDA.'" Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 708 (2d Cir. 2019) (quoting statute). In support, Bayer points to sources cited by Silver in her amended complaint indicating that the FDA was already weighing concerns over gadolinium retention in individuals with normal kidneys as early as 2009. ECF No. 140 at 17 (citing Amend. Compl. at 11, 31). The court disagrees with Bayer's characterization of the allegations. The 2009 FDA transcript hearing cited by Bayer specifically discussed elimination studies for Eovist in people with "acute kidney injury" and "chronic renal insufficiency." Amend. Compl. at 11. While Silver alleges that before 2016, Bayer "had known Gadolinium is retained in people with normal kidney function," Amend. Compl. at 31, the court fails to see where the same allegation is made about the FDA. In fact, as Bayer points out, one of Silver's cited articles included a statement by the FDA in 2018 that "clinical consequences of gadolinium retention have not been established in patients with normal renal function." ECF No. 140 at 18 n.15 (citing ECF No. 75-3 at 10). Therefore, the court overrules the objection as to the warning defect regarding the risk of gadolinium retention in individuals with healthy kidneys.

The same reasoning applies to Silver's desired warning that a linear GBCA causes more diseases than a macrocyclic one. On that matter, the court finds Bayer's argument—that information already presented to the FDA is not newly-acquired—to be convincing. In Silver's amended complaint, Silver cites 2009 FDA hearings that discussed the viability of a linear GBCA compared to the alternatives, including a macrocyclic GBCA. Amend. Compl. at 13–14. In one of the excerpts, the FDA acknowledged that "there are many that are concerned that we're going to be suggesting one is safer than other [sic]." Amend. Compl. at 14. This allegation on the face of Silver's amended complaint suggests that the information had already been presented to the FDA. As such, information regarding the viability of a linear GBCA could not be considered newly acquired information, and it could not have been a proper basis for a new label under CBE regulation. Therefore, the court departs from the R&R and grants Bayer's motion to dismiss as to the warning defect alleged in ¶ 1(b) of the amended complaint. See Amend. Compl. ¶ 1(b) (warning that "Linear Design shown to retain and promote Gadolinium caused diseases more often than Macrocyclic Design").

Finally, none of the FDA hearing transcripts indicate that the FDA already knew about the risk of gadolinium-related diseases like GDD. While Bayer argues that GDD is an unrecognized disease, Silver has presented a factual allegation, when viewed in the light most favorable to Silver, that the information would have been new and significant. The court thus allows the warning defect to proceed on the warning that Eovist can cause gadolinium-induced diseases. Amend. Compl. ¶ 1(e).

b. Clear Evidence that the FDA Would Have Rejected Labeling Changes

The R&R concluded that Bayer failed to show clear evidence that the FDA would have rejected the warning label changes. If there were such clear evidence, Silver's claims would have been precluded by federal law. Wyeth, 555 U.S. at 571. Some courts dispense with a detailed analysis of whether the FDA would have approved a change at the motion to dismiss stage because they find that such a question is almost always premature. See, e.g., Dennis, 2020 WL 534307, at *8 ("Whether or not the FDA would have rejected the label requested is not something that can be decided on the pleadings."); Gremo v. Bayer Corp., 469 F. Supp. 3d 240, 243 (D.N.J. June 29, 2020) (finding the preemption question "not properly before the Court to answer at this time"). While the R&R analyzed the claims in more detail, it reasoned along the same lines that "production or consideration of evidence outside of the complaint is generally inappropriate at this stage of the proceedings." ECF No. 125 at 17.

Bayer objects to this finding on two grounds. First, it argues that "key documents demonstrating that the FDA would have rejected Plaintiff's desired warning were attached to the Complaint itself and thus can be considered." ECF No. 140 at 19. Second, it argues that "all materials on which Bayer relies are the proper subject of judicial notice." Id.

i. Objection a

Bayer cites as its clear evidence the FDA-approved warning label from 2018 that stated "clinical consequences of gadolinium retention have not been established in patients with normal renal function." ECF No. 98 at 16–17 (referencing ECF No. 75-3 at 10). Similarly, the Eovist Medication Guide stated that "studies have not found harmful

effects in patients with normal kidneys." ECF No. 75-3 at 21. The court finds that it can take judicial notice of these materials because Silver includes and relies on these documents in her pleadings. Philips v. Pitt Cnty. Mem'l Hosp., 572 F.3d 176, 180 (4th Cir. 2009) ("In reviewing a Rule 12(b)(6) dismissal, we may properly take judicial notice of . . . documents attached to the complaint . . . ."). The court likewise takes judicial notice of FDA hearings where the agency considered whether there was such a risk. See generally ECF No. 75-13.[5] Even in the light most favorable to Silver, it is indisputable from the face of Silver's complaint that the FDA, at minimum, approved a label which stated that there has been no established risk of gadolinium retention in individuals with normal renal function, despite holding at least one hearing in 2017 to determine whether there was such a risk. Other courts have similarly concluded that evidence of the FDA's decision against recommending a warning of harm constitutes "clear evidence" that the FDA would not have approved the change in a label stating the opposite. See Smith v. GE Healthcare Inc., 2020 WL 1880787, at *7 (W.D. La. Mar. 31, 2020) (finding that the FDA's approval of a label change, which was before the court, was clear evidence that FDA would not have approved a label change which warned of such adverse effects). Put another way, Silver alleges that as of December 30, 2016, Bayer was required to warn of "[r]etention in patients with healthy kidneys." Amend. Compl. ¶ 1(a). Since the FDA approved a label that specified this was not a risk in 2018, the court finds that there is

[5] Although it appears in Bayer's objection under this section—which was purportedly about facts that appear on the face of Silver's complaint—for purposes of this motion, the court will not consider Bayer's narrative that the FDA convened a committee to discuss the potential risk of gadolinium retention and instructed all manufacturers to include the statement that clinical consequences had not been established for healthy individuals because Bayer does not point to where it is in Silver's materials—if it is at all. ECF No. 140 at 19–20.

clear evidence the FDA would not have approved Silver's desired label in 2016. Once again, Silver inclusion of extraneous information in her amended complaint defeats her own claim.

The R&R mentions that its recommendation against finding preemption is consistent with the rulings of other courts, including the Western District of North Carolina. ECF No. 125 at 17 (citing Dennis, 2020 WL 534307, at *8). The court recognizes that Dennis is one of the rare instances that a sister court in the Fourth Circuit has addressed GBCA claims; however, this case is distinguishable. Nothing in Dennis indicated that the plaintiff had affirmatively pled evidence showing the FDA's resistance to recognizing gadolinium retention. Rather, the Dennis court focused on whether the defendant knew or should have known about the risks based on studies that had been published. Id. If anything, Silver's extensive discussion about the risks of gadolinium retention in healthy individuals that were known as early as 1997 makes it even more evident that the FDA was not going to approve a label warning. See Amend. Compl. at 17 ("Defendants have known at least since 2006 (perhaps as long as since 1997) that Eovist is retained . . . ."). Based on the record evidence here, the court does not consider the Dennis court's determination—that it was premature to resolve the issue of whether the FDA would have rejected the label—as one and the same. The court therefore departs from the R&R and grants Bayer's motion to dismiss as to the warning defect about gadolinium retention in individuals with healthy kidneys. Amend. Compl. ¶ 1(a).

ii. Objection b

The court finds that it is capable of making the determination to dismiss Silver's warning defect claim without looking to any of the documents that Bayer seeks to have

judicially noticed. As such, the court finds it is unnecessary to decide whether the documents are subject to judicial notice, and it will not consider the documents in the context of the instant motion.

2. State Law Claim

Since the court finds that Silver's warning defect claim is preempted by federal law, it need not reach the merits of the claim under South Carolina law. Bayer raises no objections directly related to the desired warning about gadolinium disease, which is the only alleged warning defect remaining. Additionally, the court has already ruled that any dispute over the reasonable foreseeability of Silver's alleged injuries is premature. ECF No. 125 at 24 (citing Pierik, 2019 WL 4686551, at *2). Silver will be allowed to proceed with her warning defect claim solely under the theory that Bayer should have included a warning label that Eovist can "[c]ause Gadolinium-induced diseases for which there are no known cures." Amend. Compl. ¶ 1(e).

C. Strict Liability (Count 4) and Criminal/Gross Negligence (Count 5)

Under Count 4, the R&R recommended against dismissing Silver's strict liability claim. It analyzed the claim under the general requirements of a products liability action, in which the plaintiff must show (1) an injury, (2) that the product was in essentially the same condition as it was when it left the defendant's possession, and (3) that the injury occurred because the product was in a defective condition unreasonably dangerous to the user. Graves, 735 S.E.2d at 658. Bayer raises no additional objections that the court has not already discussed, so the court will permit Silver's strict liability claim to proceed.

Under Count Five, the R&R found that South Carolina does not appear to recognize a civil claim for criminal negligence. ECF No. 125 at 26 (citing Shields v. S.C.

Dep't of Highways & Pub. Transp., 401 S.E.2d 185, 190 (S.C. Ct. App. 1991) (Littlejohn, J. dissenting)). Instead, the R&R recommended construing Count Five as a claim for gross negligence only. The court finds no clear error in this approach.

In addition to the three elements that are sufficient to establish a strict products liability claim, "[a] negligence theory imposes the additional burden on a plaintiff 'of demonstrating the defendant (seller or manufacturer) failed to exercise due care in some respect, and, unlike strict liability, the focus is on the conduct of the seller or manufacturer, and liability is determined according to fault.'" Branham, 701 S.E.2d at 9 (quoting Bragg v. Hi-Ranger, Inc., 462 S.E.2d 321, 326 (S.C. Ct. App. 1995)). On top of that, "[g]ross negligence is the intentional conscious failure to do something which it is incumbent upon one to do or the doing of a thing intentionally that one ought not to do." Bass v. S.C. Dep't of Soc. Servs., 780 S.E.2d 252, 258–59 (S.C. 2015) (citations omitted).

The R&R determined that under Count 5, Silver alleged facts that Bayer knew of the danger of gadolinium for at least ten years but did not warn of these "unknown" risks until 2018. ECF No. 125 at 27 (citing Amend. Compl. at 22). Instead of responding to the claim, Bayer explains that the gross negligence claim is solely based on an alleged failure to warn and chooses to stand on its arguments regarding the failure to warn claim. ECF No. 140 at 2 n.3. The court finds that the R&R was providing an example of a well-pleaded fact, and Silver pleads other facts that could be construed as a design defect under strict liability, like the statement that "Gadolinium has toxic effects. There is no treatment for Gadolinium retention." Amend Compl. at 24. Silver need not be constrained to a particular theory, and Bayer has failed to advance any other relevant

objection. Construing the pleadings liberally, the court finds that Silver has stated a claim for gross negligence.

D. Objection Under Rule 8(a)

Finally, Bayer argues that "the R&R declined to consider Bayer's argument that Plaintiff fails to satisfy Rule 8(a)" by failing to set forth a short and plain statement of her claims. ECF No. 140 at 4. Bayer asks that the court dismiss Silver's complaint based on Silver's decision to attach over a thousand pages, which Bayer claims far exceeds the page count of many complaints that federal courts in the country has dismissed under Rule 8(a)(2). Id. at 32. The court first notes that Silver's decision to attach an overwhelming number of exhibits led to the dismissal of a claim that, based on the amount of discussion in the briefs, appears to be central to Silver's claims. Second, though the court has not referenced it directly to this point, the court notes that pro se complaints and petitions are held to a less stringent standard than those drafted by attorneys.[6] Finally, when weighing a Rule 8(a) dismissal, courts have also considered whether the complaint—as opposed to the addenda and exhibits—is overly lengthy and whether the complaint runs afoul of other rules, such as being "verbose, confusing and almost entirely conclusory." Hearns v. San Bernardino Police Dep't, 530 F.3d 1124, 1130 (9th Cir. 2008) (quoting Nevijel v. N. Coast Life Ins. Co., 651 F.2d 671, 674 (9th Cir. 2008)). Outside of the superfluous exhibits, the court does not find Silver's complaint to be unacceptable. For those reasons, the court finds that it need not exercise

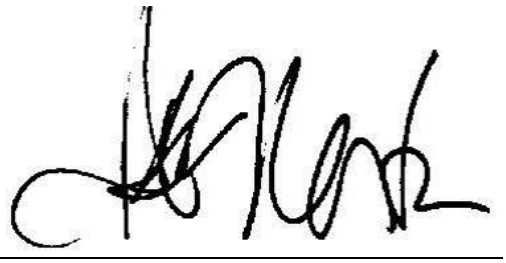
[6] Products liability actions are expensive, hard fought, and will require the testimony of expert witnesses. As such, the court urges Silver to obtain an attorney, particularly in advance of potential summary judgment proceedings on her remaining claims.

its discretion to dismiss the complaint. However, the court advises Silver to be mindful of the procedural rules in the future.

IV. CONCLUSION

For the foregoing reasons the court **ADOPTS IN PART AND REJECTS IN PART** the Magistrate Judge's R&R and **GRANTS IN PART AND DENIES IN PART** Bayer's motion to dismiss in accordance with this order.

AND IT IS SO ORDERED.



DAVID C. NORTON
UNITED STATES DISTRICT JUDGE

September 30, 2021
Charleston, South Carolina